REMARKS

This Amendment/Response is in response to the Final Office action (Unnumbered Paper) mailed 28 May 2009.

Claims 1-4, 6-9, 11, 13-14 and 16-17 are pending and under the Examiner's consideration.

Claims 1, 8, 11, 14 and 17 have been amended by this Amendment.

No new matter has been added.

I. Claim Rejections – 35 USC § 112

Claims 1-4, 6-9, 11 and 13-17 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 8, 11, 14 and 17 are amended by deleting "Purified Leukocyte Dialysate Subfraction" in order to expedite the prosecution. The applicant does not disclaim any of the subject matters of the claims as filed on March 23, 2009.

The definition of "Purified Leukocyte Dialysate Subfraction" should be read in the specification of the instant application in which the prior art references are incorporated. The examiner did not consider fully both the instant application and the incorporated prior art references.

Particularly, in the definition section of the instant specification, the purified Leukocyte Dialysate Subfraction was described as follows, and the purified Leukocyte Dialysate Subfraction does not mean any one of the purified leukocyte dialysate subfractions:

> "[0041] The "selected immunoregulators" ("selected immunomodulators" "selected immunoamplifiers") include the purified Leukocyte Dialysate Subfraction (LDS) described by Dr. A. Arthur Gottlieb Patents (U.S. Pat. Nos. 5,100,663, 4,616,079, 4,699,898, 4,710,380, 4,778,750, 4,874,608, 5,013,546, 5,081,108, 5,093,321 which are incorporated herein by references) which is naturally derived from healthy human leukocytes, as well as purified immunologically active components of the naturally derived immunoregulators including the dipeptide tyrosylglycine (YG) and the tripeptide tyrosylglycylglycine (YGG), as well as synthetically produced YG and YGG. These regulators also include covalently modified YG and YGG, such modifications designed to stabilize or to enhance the biological activity of said regulators, as well as pharmaceutically acceptable salts, suitable for human use, of YG, YGG, and related molecules including covalently modified YG, and covalently modified YGG." (emphasis added)

In response to the above definition, the examiner argued that:

> "please note that Applicant's arguments center around the definition of leukocyte dialysate subfraction as being "naturally derived from health human leukocytes, as well as purified immunologically active components of the naturally derived immunoregulators including the dipeptide tyrosylgycine (YG) and the tripeptide tyrosylglycylglycine (YGG), as well as synthetically produced YG and YGG". However, the instant claims are already drawn to YG and YGG, therefore the making and using of the purified leukocyte dialysate subfraction, and how it differs from YG and YGG, is not adequately described, after carefully considering all the patents incorporated by reference."

Here, since a pharmaceutical composition of Purified Leukocyte Dialysate Subfraction includes YG and/or YGG, the administration to the individual a pharmaceutical composition of Purified Leukocyte Dialysate Subfraction will be within the scope of the administration to the individual a pharmaceutical composition of YG-Product, YGG-Product, or a combination thereof.

However, even if the instant claims are already drawn to YG and YGG Products, the recitation of "Purified Dialysate Subfraction" which contains YG and/or YGG does not render the scope of the claim unclear.

MPEP §2173.05(h) specifically states that:

> "Similarly, the double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. Rather, the facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim renders that claim indefinite. The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear. For example, the Markush group, "selected from the group consisting of amino, halogen, nitro, chloro and alkyl" should be acceptable even though "halogen" is generic to "chloro."

Thus, there is nothing wrong in the recitation of "YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction, and a combination thereof" even if the instant claims are already drawn to YG-Product and YGG-Product.

In order to expedite the prosecution, however, the applicant deletes the "Purified Leukocyte Dialysate Subfraction" from the claims without limiting the scope of claims.

In view of the above, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Reconsideration of the rejections and objections is requested. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

No fee is incurred by this Amendment.

Respectfully submitted,

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